

In the Claims

The following listing of the claims replaces all previous listings.

1. (Currently Amended) A device for automatically retracting a needle used to introduce a cannula of a subcutaneous infusion device into a subcutaneous layer of skin of a patient, the device comprising:
  - a housing defining an internal cavity;
  - a needle hub coupled to the housing and including a needle, the needle being coupled to a cannula of a subcutaneous infusion device, and the needle hub including barbs coupling the needle hub to the housing;
  - a spring configured to move the needle into a retracted state; and
  - a trigger member including projections;wherein, upon full introduction of the needle and associated cannula of the subcutaneous infusion device into a subcutaneous layer of skin of a patient, the projections come in contact with the barbs of the needle hub and force the barbs to release the needle hub from the housing, and the spring automatically moves the needle hub and associated needle into the internal cavity of the housing into the retracted state while leaving the cannula of the subcutaneous infusion device in the subcutaneous layer of skin of the patient.
2. (Original) The device of claim 1, further comprising a second spring configured to introduce the needle and associated cannula of the subcutaneous infusion device into the subcutaneous layer of skin of the patient.
3. (Original) The device of claim 1, wherein the housing includes a first portion coupled to the needle, and a second portion that is slideably received in the first portion, wherein the first portion slides relative to the second portion to introduce the needle into the subcutaneous layer of skin of the patient.
4. (Original) The device of claim 1, further comprising means for covering the needle prior to introduction of the needle into the subcutaneous layer of skin of the patient.

5. (Original) The device of claim 1, further comprising a sleeve coupled to the housing to cover the needle prior to introduction of the needle into the subcutaneous layer of skin of the patient.
6. (Original) The device of claim 1, wherein the device is configured to allow the subcutaneous infusion device to be preloaded into the device.
7. (Original) The device of claim 1, further comprising a cap that is coupled to the housing of the device.
8. (Original) The device of claim 7, wherein the cap includes a tamper-evident seal.
9. (Currently Amended) A device for inserting a subcutaneous infusion device into skin of a patient, comprising:
  - a housing;
  - a hub coupled to the housing and defining an interior passage;
  - a needle hub including a needle, the needle hub being positioned in the interior passage of the hub and including barbs that couple the needle hub to the housing so that the needle hub is held in a fixed position relative to the hub and the housing;
  - a sleeve;
  - a spring engaging the needle hub;
  - a trigger member including projections; and
  - a cap configured to be coupled to the housing, the cap including a tamper-evident band, wherein the tamper-evident band remains coupled to the housing when the cap is removed from the housing;

wherein the housing, hub, and needle hub are movable relative to the sleeve to introduce the needle of the needle hub and associated cannula of an infusion device into a subcutaneous layer of skin, and wherein, upon the needle and associated infusion device being fully inserted into the subcutaneous layer of skin, the projections come in contact with the barbs of the needle hub and force the barbs to release the needle hub so that the needle hub is slideable relative to the

hub, and the needle hub including the needle are moveable by the spring through the passage of the hub to a retracted state, leaving the infusion device positioned on the skin of the patient.

10. (Canceled)

11. (Canceled)

12. (Original) The device of claim 9, further comprising another spring engaging the needle hub, the spring being positioned to automatically introduce the needle of the needle hub and associated cannula of the infusion device into the subcutaneous layer of the skin of the patient.

13. (Original) The device of claim 9, wherein the device is configured to allow the subcutaneous infusion device to be preloaded into the device.

14. (Original) A device for inserting a subcutaneous infusion device into skin of a patient, comprising:

a housing including a closed upper end, defining an open lower end, and a threaded portion positioned adjacent the open lower end;

a cylinder hub including first and second ends, the cylinder hub defining an interior passage and two opposing slots extending from a mid-portion of the hub to the first end, and the cylinder hub defining opposing apertures adjacent the second end of the cylinder hub, wherein the first end of the cylinder hub is coupled to the upper end of the housing;

a needle hub including a main body with first and second ends, and a needle coupled to the main body, the main body including opposing wings formed at the first end and opposing barbs at the second end, wherein the needle hub is positioned in the interior passage of the cylinder hub such that the opposing wings extend through the opposing slots of the cylinder hub, and the opposing barbs of the needle hub extend through the opposing apertures of the cylinder hub and engage the cylinder hub so that the needle hub is held in a fixed position relative to the cylinder hub and the housing;

a sleeve including first and second ends and defining an interior passage, the sleeve including opposing projections extending inwardly into the interior passage of the sleeve at a

mid-portion of the sleeve, and a cylindrical shoulder formed in the interior passage at the mid-portion of the sleeve, wherein the second end of the cylinder hub extends through the passage of the sleeve, and a portion of the sleeve including the first end is received within the housing;

a spring with first and second ends, wherein the spring surrounds the cylinder hub and extends within the passage of the sleeve, and wherein the first end of the spring is seated on the shoulder of the sleeve, and the second end of the spring engages the opposing wings of the needle hub extending through the opposing slots of the cylinder hub; and

a cap including a closed first end, defining an open second end, and a threaded portion positioned adjacent the open second end, wherein the threaded portion of the cap is threaded onto the threaded portion of the housing to seal the device;

wherein, upon removal of the cap from the housing, the second end of the sleeve is positioned relative to skin of a patient, and the housing, cylinder hub, and needle hub are moved relative to the sleeve in a direction towards the skin of the patient so that the needle of the needle hub and associated cannula of an infusion device are introduced into a subcutaneous layer of the skin, and wherein, upon the needle and associated infusion device being fully inserted into the skin and the cylinder hub being moved relative to the sleeve, the opposing projections of sleeve contact and force the barbs of the needle hub inwardly until the barbs disengage from the opposing apertures of the cylinder hub, and wherein upon disengagement of the barbs from the cylinder hub, the needle hub including the needle are moved by the spring through the passage of the cylinder hub to the first end of the cylinder hub adjacent the closed upper end of the housing, leaving the infusion device positioned on the skin of the patient.

15. (Currently Amended) A device for inserting a subcutaneous infusion device into skin of a patient, comprising:

a housing;

a needle coupled to the housing for receiving a cannula of a subcutaneous infusion device; and

a cap coupled to the housing, the cap including a tamper-evident band that is coupled to the cap by a plurality of tabs extending about the taper-evident band, wherein the tabs break when the cap is removed from the housing, and wherein the tamper-evident band remains coupled to the housing when the cap is removed from the housing;

wherein the needle is inserted through the cannula of the subcutaneous infusion device and is introduced into the skin of the patient to insert the cannula into the skin; and  
wherein the cap is coupled to the housing prior to use to create a sterile environment.

16. (Original) The device of claim 15, wherein the cap is coupled to the housing after use to protect against exposure to the needle.

17. (Currently Amended) A method for retracting a needle of a device used to introduce a cannula of a subcutaneous infusion device into a subcutaneous layer of skin of a patient, the method comprising:

removing a cap from the device, the cap including a tamper-evident band, wherein the tamper-evident band remains coupled to [[the]] a housing when the cap is removed from the housing;

introducing a cannula of a subcutaneous infusion device into a subcutaneous layer of skin of a patient using a needle of a device; [[and]]

upon the full insertion of the cannula by the device and the device reaching a trigger state, allowing projections within the device to move opposing barbs towards one another to release the needle from the housing; and

automatically retracting the needle while leaving the infusion device positioned on the skin of the patient.

18. (Original) The method of claim 17, further comprising reapplying the cap after introduction of the cannula.

19. (Original) The method of claim 17, further comprising preloading the infusion device in the device prior to application of the cap.

20. (Original) The method of claim 17, wherein the step of introducing the cannula further comprises providing a member in the device to automatically introduce the cannula of the subcutaneous infusion device into the subcutaneous layer of skin of the patient using the needle.

21. (Original) The method of claim 17, further comprising preloading the subcutaneous infusion device into the device.

22. (Currently Amended) ~~A method for inserting a subcutaneous infusion device into skin of a patient~~ The method of claim 17, further comprising:

~~providing a housing and a needle coupled to the housing for receiving a cannula of a subcutaneous infusion device~~

~~positioning the cannula of the subcutaneous infusion device on the needle;~~

~~coupling [[a]] the cap to the housing to create a sterile environment;~~

~~providing [[a]] the tamper-evident band coupled to the cap by tabs;~~

~~coupling the tamper-evident band to the housing; and~~

~~uncoupling the cap from the housing so that the tabs are broken and the tamper-evident band remains coupled to the housing.~~

23.-25. (Canceled)